



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

OCT 28 2004

349 104 -4 2007

Amha Belay, Ph.D.  
Senior Vice President/Scientific Director  
Earthrise Nutritionals, Inc.  
2151 Michelson Drive  
Suite 258  
Irvine, California 92612

Dear Dr. Belay:

This is in response to your letter of October 12, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that you are making the following claims, among others, for the following product:

Aller-Bye      "[I]nhibits histamine production by mast cells." [S]upport the immune system's natural inflammatory response." "[M]odulates the immune system for a healthy inflammatory response. The inflammatory response is the natural response of the immune system against any attack by foreign elements."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, including the derived name Aller-Bye, suggest that it is intended to treat, prevent, or mitigate diseases such as allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

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Please contact us if you require further assistance.

Sincerely yours,

*for Robert Moore*

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Compliance, HFR-PA240

EARTHRISE

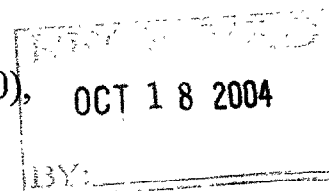
**Earthrise Nutritionals, Inc.**

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October 12, 2004

Susan J. Walker, M.D., Director,  
Division of Dietary Supplement Programs (HFS-810),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
Department of Health & Human Services  
5100 Paint Branch Parkway,  
College Park, MD 20740



**Re: Notification of Structure/Function Statements – Aller-Bye®**

Dear Dr. Walker,

As per 21 CFR section 101.93, this letter is a notification of new structure/function claims to be made on labels, brochures and collateral materials of the following Earthrise Nutritionals dietary supplement: Aller-Bye®. The structure-function statements are listed on the enclosed attachment.

Manufacturer/Packer/Distributor: Earthrise Nutritionals, Inc.

The firm believes it has substantiation, and the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me at (760) 348-5027 extension 21.

Sincerely yours,

Amha Belay, Ph.D.  
Senior Vice President/Scientific Director

Enclosure

October 12, 2004

**Structure/Function Statements For Earthrise Nutritionals, Inc.**  
**Aller-Bye<sup>®</sup> Dietary Supplement**

OCT 18 2004

**Aller-Bye<sup>®</sup>**: (Capsule)

**Ingredients:** Earthrise<sup>®</sup> Spirulina Gold<sup>®</sup> (*Spirulina (Arthrospira) platensis*) and Vitamin C.

**i) Immune & Respiratory Health Structure/Function Statements**

- Supports respiratory health\*
- Supports healthy immune system, sinus and respiratory tract.\*
- Earthrise<sup>®</sup> Aller-Bye<sup>®</sup> : a natural Spirulina-based, proprietary product which supports the immune system.\*
- A clinical study shows that Earthrise Aller-Bye<sup>®</sup> balances the immune system naturally. Further studies show that Spirulina supports healthy respiratory function.\*

**ii) Immunomodulation Structure/Function Statements**

- Earthrise<sup>®</sup> Aller-Bye<sup>®</sup> modulates the immune system by supporting normal IL-4 levels.\*
- Earthrise<sup>®</sup> Aller-Bye<sup>®</sup> is a Spirulina-based proprietary blend which modulates the immune system by supporting healthy IgE levels.
- Inhibits IgE production.\*



**Earthrise Nutritionals, Inc.**

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-Earthrise® Aller-Bye® is a Spirulina-based proprietary blend which inhibits histamine production by mast cells.\*

-The ratio/balance of two types of immune T-helper cells (called Th<sub>1</sub> and Th<sub>2</sub>) is important for healthy immune function. Earthrise® Aller-Bye® provides immune health by supporting a healthy ratio/balance of Th<sub>1</sub> and Th<sub>2</sub> cells.\*

**iii) Immune & Inflammatory Response Structure/Function Statements**

-Earthrise® Aller-Bye® is a natural Spirulina based proprietary product that is clinically shown to support the immune system's natural inflammatory response.\*

-Studies have shown that Earthrise® Aller-Bye® modulates the immune system for a healthy inflammatory response. The inflammatory response is the natural response of the immune system against any attack by foreign elements. Reports from clinical studies also suggest that this Spirulina based product supports a healthy respiratory function.\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

**E N D**